



NOV 17 2004

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Corporate Intellectual Property UW220
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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,002,953

#22

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,002,953, which claims the human drug product Avandia® (rosiglitazone maleate), and a method of use of said product, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,113 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,113 days.

Under 35 U.S.C. § 156(c), if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 13, 2003 (68 Fed. Reg. 7381), the period of extension would be:

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,859 - 0) + 183 \\ &= 1,113 \text{ days}\end{aligned}$$

Since the regulatory review period began on October 23, 1993, after the patent issued (March 26, 1991), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the 14 year limitation of 35 U.S.C. § 156(c)(3) nor the limitations of 35 U.S.C. § 156(g)(6) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,002,953
Granted:	March 26, 1991
Original Expiration Date ¹ :	August 30, 2008
Applicant:	Richard M. Hindley
Owner of Record:	SmithKline Beecham Corporation

¹Subject to the provisions of 35 U.S.C. § 41(b).

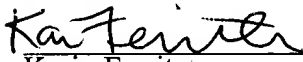
Title: Compounds
Classification: 514/275
Product Trade Name: Avandia® (rosiglitazone maleate)
Term Extended: 1,113 days
Expiration Date: September 17, 2011

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7744
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744.


Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

RE: Avandia® (rosiglitazone maleate)
FDA Docket No.: 00N-1249

Attention: Claudia Grillo